

REMARKS

Rejection of Claims and Traversal Thereof

In the September 16, 2008 Office Action:

claims 60-61 and 63-64 were rejected under 35 U.S.C. §103(a) as being unpatentable over JP 06-070698; (hereinafter Sugimoto) and

claim 62 was rejected under 35 U.S.C. §103(a) as being unpatentable over Sugimoto as applied above in view of Place et al. (US Patent No. 6,6261,590, hereinafter Place).

These rejections are hereby traversed and reconsideration of the patentability of the pending claims is therefore requested in light of the following remarks.

Rejections under 35 U.S.C. §103(a)

Claims 60-61 and 63-64 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sugimoto. Applicants submit that Sugimoto does not in any way meet the necessary requirements to establish a *prima facie* case of obviousness.

Initially, it should be noted that applicants believe that the Office did not respond to all the issues raised by applicants in the previously filed response. For example, the Office completely overlooked and provided no excuse for not addressing the conversion of the carotenoid values from Sugimoto which is 3 mg to 100mg/100g of feed. Applicants question why the Office has not addressed the calculation for the carotenoid in the feed. Avoiding the proof that Sugimoto only teaches 0.003% to 0.1% is not sufficient to meet the requirements of addressing applicants' previous evidence in the form of mathematical calculations.

The limitations of method claim 60 and claims depending therefrom include the following:

A method of preparing an animal feed composition, the method comprising (a) mixing a carotenoid and **an algal derived DHA-rich phospholipid** that is liquid at the body temperature of the animal to form a mixture; and (b) thereafter combining the mixture with at least one other animal feed component, **such that the carotenoid makes up at least 1%, by weight, of the**

composition and the phospholipid makes up at least 5%, by weight, of the composition.
(emphasis added)

Thus, the feed composition must include at least **1% by weight of the carotenoid** and at least **5% of the DHA-rich phospholipid**. The Sugimoto reference does not in any way describe, teach or suggest these types or levels of components.

Instead, the Sugimoto reference clearly describes a range for the use of the carotenoid as recited on paragraph [012] it is stated the following;

“[0012]Although it is 0.1g/100g feed -10g/100g feed, quantity added in feed is added so that it may become the amounts 2g-10g of phospholipid/100g feed, and the amount of carotenoid **of 3 mg - 100 mg/100g feed preferably.**” (emphasis added)

As such, the Sugimoto range for the **phospholipid in a feed composition is 0.1 % to 10% and preferably from 2% to 10%**. More important, it must be recognized by the Office that the range for the **carotenoid is from 0.003% to 0.1% in the feed composition.**

Notably in the Office Action of September 16, 2008, the examiner did not seem to recognize the simple conversion from weight units to percent units, and as such, the conversion is shown below wherein “C” represents carotenoid:

$$3 \text{ mg of C} = \frac{1 \text{ g of C}}{1000 \text{ mg of C}} = 0.003 \text{ g of C.}$$

$$\frac{0.003 \text{ g of C}}{100 \text{ g of Feed}} \times 100\% = 0.003 \%$$

And

$$100 \text{ mg of C} = \frac{1 \text{ g of C}}{1000 \text{ mg of C}} = 0.1 \text{ g of C.}$$

$$\frac{0.1 \text{ g of C}}{100 \text{ g of Feed}} \times 100\% = 0.1 \%$$

Thus, one can see that Sugimoto teaches from 0.003% to 0.1% of carotenoid in the 100 g of feed.

Notably, as previously stated, the Sugimoto group found low percentages of carotenoids in the feed composition to be very effective, and as such, why would one skilled in the art be motivated to change the amount of carotenoids in the feed compositions. Notably the examples of Sugimoto showed that 10 mg of carotenoids in 100 g of feed (.01% by weight) was effective to reduce the level of formed peroxide (see Table 1, composition (3)).

[0016]Experimental plot : (1) 3% of a soybean lecithin. (2) Astaxanthin 10mg/100g feed. (3) Process and carry out a vacuum packing to all the fish picking raisings and a fillet at the time of the administration division test termination of a frozen sardine which carried out 10 mg of 3% of 3% of soybean lecithin + astaxanthin 10mg/100g feed (4) soybean lecithin + beta-carotene/100g feed (5) additive-free control plot (6) cutting, -The color of a dark-flesh muscle,

Notably with the 10mg/100 feed or 0.01% of carotenoid (Sample 3) there was a marked reduction in peroxide concentration of the lipids in the muscles as shown below in Table 1. Notably, lowering the peroxide level reduces smell and blackening of the fish tissue.

[Table 1]

表1 ブリ筋肉の官能評価と筋肉脂質の過酸化物質濃度

試験区	血合筋の鮮やかさ	味	臭い	過酸化物質濃度 nmol /mg脂質
1	41	42	40	0.31 (±0.12)
2	35	36	40	0.66 (±0.34)
3	48	48	47	0.18 (±0.10)
4	47	46	48	0.21 (±0.13)
5	31	35	33	1.10 (±0.75)
6	12	22	11	1.82 (±0.51)

In example 3, Table 3, again the only amount of carotenoid used was 10 mg per 100 grams of feed (.01% of the feed composition).

[0023]experimental plot: -- (1) soybean-lecithin 3%(2) soybean-lecithin 3%+ astaxanthin 10mg/100g feed (3) soybean-lecithin 3%+ opossum shrimp 20%(4) additive-free control plot

[Table 3]

表3 マダイ筋肉毛細血管のメラニン色素沈着の有無 (c m)

試験区	採材部位	S-1	S-2	S-3	合計
(1) 大豆レシチン 3%		12	10	16	38
(2) 大豆レシチン 3% アスタキサンチン 10mg		3	6	0	9
(3) 大豆レシチン 3% イサザアミ 20%		8	5	5	18
(4) 無添加対照区		78	64	54	196

Clearly, sample 2 with (10mg/100g or feed) 0.01% of carotenoid was effective in reducing the negative color effect of the tissue. Thus, as stated above, this reference provides no indication or motivation to change the amount of carotenoids in a feed composition.

According to the Office:

It is also not the general teaching of Sugimoto. The general teaching is the ratio is 0.1g-10g of carotenoid to 100g of phospholipid and that the feed composition contain more than 2g of phospholipid and not less than 3mg of carotenoid in the feed of 100g. The teaching is present in the specification and in the claims (paragraph 6, 10, claims 1-4) as well as a teaching that the amounts can be modified (optimization) and adjusted for the components of the feed and color desired (paragraph 12-14, Technical field, Means for Solving the Problem-1st paragraph). As a result, the claimed ranges are within the prior art and it is well within the skill of one in the art to adjust within the ranges taught in Sugimoto to arrive to the instant claims.

Emphasis added

Applicant insists that the statement by the Office that “it is well within the skill of one in the art to adjust within the ranges taught in Sugimoto to arrive to the instant claims” **is not applicable in the present situation especially** when unexpected results are found.

Applicant has provided unexpected and superior results by using the feed of the present invention that include DHA-rich phospholipids in combination with the correct amount of carotenoid. Notably, Sugimoto teaches the use of soy lecithin but never consider using a DHA-rich phospholipid.

Clearly, almost a 40% increase in the incorporation of the carotenoid into the fish by using the algal derived DHA-phospholipids by applicants is totally unexpected.

Improved Total Carotenes (TC) Assimilation With DHA-PL (Trout)

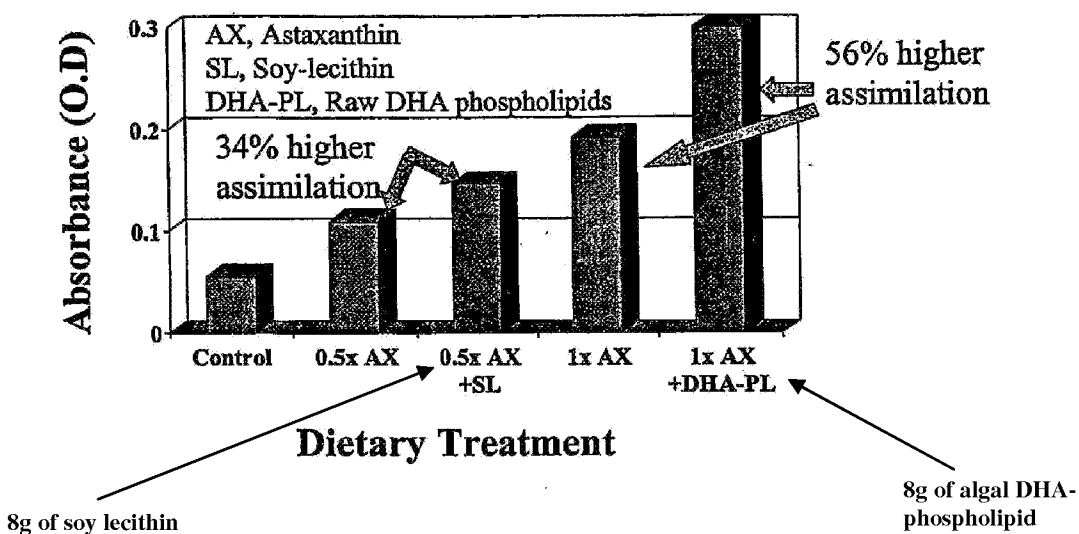


Figure 1 set forth above shows the improved total carotenoid content of rainbow trout using conditions as described in Example 5 (for the Astaxanthin compared to Astaxanthin+DHA-phospholipid and using 8g of the algal DHA-phospholipid) and Example 4 (for Astaxanthin compared to Astaxanthin +soy lecithin and using 8g of the soy lecithin). The control had no added astaxanthin in the diet (some residual carotenoids were in the original diet). The soy lecithin gave a 34% higher incorporation of astaxanthin (AX) than AX alone. However, the DHA-rich phospholipid gave 56% higher incorporation of AX than AX alone and almost 100% greater absorption than using the soy lecithin. **It is important to note that both the compositions of Example 4 and 5 contain exactly the same amount of a phospholipid but the one that is derived from algal and included DHA-rich phospholipids is surprisingly more effective in aiding the absorption of the carotenoid.**

According to the Office, applicants used routine experimentation to find the optimal range. However, the Office completely avoided the case law rulings that expressly state that “if unexpected results are found then in fact the results are not obvious.” As the Court stated in *In re Russell*, 169 USPQ, 412 (CCPA 1971) “if appellant can establish that his relatively narrow ranges yield unexpectedly superior results as against the broad Wei ranges as a whole, appellant will have established unobviousness of the claimed invention.”(See *In re Luvisi*, 144 USPQ 646 (CCPA 1965); *In re Neave*, 152 USPQ 274 (CCPA 1967)).

The *Russell* court then went further to discuss the prior art and what it taught and whether applicants’ results would be unexpected in view of the cited reference, such as in this situation Sugimoto. Specifically, the *Russell* Court looked at the examples of the prior art to determine the line of guidance and teachings one skilled in the art would gain therefrom. Also the specification and statements made in the prior art were considered relevant by the *Russell* Court. Clearly the examples in Sugimoto teach that the use of soy lecithin is an acceptable phospholipid and the amount of carotenoid does not reach the at least 1% as recited by applicants’ claim 60.

The *Russell* court concluded that “despite the fact that some of the claimed compositions are within the broad teachings of the prior art,” they ruled that because the applicants’ compositions showed unexpected advantageous properties that such compositions would not have been obvious. In light of this ruling, applicants insist that the presently claimed feed compositions made by the claimed invention are not obvious in light of Sugimoto.

Notably, all evidence of record that establishes nonobviousness must be considered by the Office, and **thus all the evidence set forth in the present application as filed** must be considered when determining patentability. This remarkably higher effectiveness with the use of algal derived DHA-rich phospholipids is wholly unexpected in light of the fact that Sugimoto composition teaches a phospholipid. There is no basis in law for ignoring any **property** in making such a comparison. An assumed similarity based merely on a comparison of formulae must give way to evidence that the assumption is erroneous. (See *In re Papesch*, 137 USPQ 43 (CCPA 1963)). To provide guidance regarding to the types of evidence that must be considered, the *Papesch* Court stated that such evidence may include data showing that a compound is **unexpectedly superior in a property that it shares with prior art compounds**. Applicants have provided such data by the showing of unexpected results by using a specific type of phospholipid. It should be known that evidence that a compound is unexpectedly superior in one of a spectrum of common properties is sufficient to overcome a rejection for lack of inventive step. *In re Chupp*, 2 USPQ2d 1437 (CAFC 1987). The presently claimed compound possesses unexpectedly improved properties.

For these reasons, the Office has not met its burden of establishing a *prima facie* case of obviousness. The applicants therefore request that the rejection of claims 60-61 and 63-64 on the basis of obviousness be withdrawn.

2. Claim 62 rejected under 35 U.S.C. §103(a) as being unpatentable over Sugimoto in view of Place. Again applicants insist that neither reference alone or in combination defeats the patentability of the presently claimed invention. The shortcomings of Sugimoto, as discussed above, are not overcome by the introduction of Place. Applicants submit that the Office has not established a *prima facie* case of obviousness and requests that all rejections under section 103 be withdrawn.

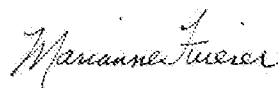
2nd Month Filing after Final Office Action

The 2nd month deadline was November 16, 2008 but because that date falls on a Sunday the time period is extended to November 17, 2008.

Conclusion

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Huang reconsider the patentability of the pending claims in light of the distinguishing remarks herein, and withdraw all rejections, thereby placing the application in condition for allowance. If any issues remain outstanding incident to the allowance of the application, Examiner Huang is requested to contact the undersigned attorney at (919) 286-8089.

Respectfully submitted,



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